

LAW OFFICE OF  
MARK R. BUSCHER  
703 753 5256 (TEL)  
703 753 9852 (FAX)

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## FACSIMILE TRANSMITTAL SHEET

TO:	Mail Stop Amendment	FROM:	Mark R. Buscher
COMPANY:	USPTO	DATE:	5/4/2005
FAX NUMBER:	(703) 872-9306	TOTAL NO. OF PAGES INCLUDING COVER:	4+1
PHONE NUMBER:		SENDER'S REFERENCE NUMBER:	
RE:	USSN:10/660,775	YOUR REFERENCE NUMBER:	SYN-0032

Attached are:

1. Response to Restriction Requirement (4 pages)

P.O. Box 161, Catharpin, VA 20143

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MAY 04 2005

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of

Raymond J. H. WESTHEIM.

Serial No. 10/660,775

Filed: Sept. 12, 2003

For: Bicalutamide Forms

: Examiner: SHIAO, Robert

: Group Art Unit: 1626

: Docket No.: SYN-0032

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner of Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

May 4, 2004

Sir:

In the Office Letter dated April 4, 2005, the Examiner in charge of the above-identified application made a restriction requirement and an election of species. Specifically, the Examiner required restriction to one of the following groups of claims:

- I. Claims 1-10 and 14-22 drawn to crystalline form II compound and compositions.
- II. Claims 11-13 drawn to crystalline or amorphous compound/compositions.
- III. Claim 23, in part, drawn to a method of use.
- IV. Claims 24-27, in part, drawn to a process of making a compound of form II.
- V. Claim 28, in part, drawn to a process of making a compound of form II.
- VI. Claim 29, in part, drawn to a process of making an amorphous compound.

Within each group the Examiner has required election of a single compound or species. These requirements are respectfully traversed.

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The Examiner has apparently miss-read the claims in the present application. Contrary to the Examiner's rationale, none of the instant claims contains a Markush group. Far from the "compounds" having "diverse chemical structure" (see Office letter page 5, lines 1-4), all claims recite a single chemical compound known as bicalutamide in various forms; e.g. crystalline, amorphous, etc. The bicalutamide molecule in crystalline form II (claim 1) has the same, not a "diverse," chemical structure as the bicalutamide molecule in an amorphous form (claim 12). Accordingly, the Examiner's whole factual basis for the restriction is clearly in error.

Furthermore, the Examiner has failed to establish that the 6 groups of claims are independent and distinct or that a serious burden would be imposed by search and examination of all claims. Indeed, the analysis of related inventions and when restriction is proper, as laid out in MPEP § 800, have been ignored by the Examiner. Instead, the Examiner merely asserts that the claims "differ in elements, starting materials, dose, administration, bonding arrangement and chemical property to such an extent that reference anticipating compounds of any one group would not render another group obvious." (See Office Letter bridging pages 5-6). But the different groups do not relate to different chemical compounds as the Examiner's rationale presupposes. Moreover, such a rationale, even if true, is not a basis for restriction; i.e. not proof of independency and distinctness. And, the Examiner is in fact wrong in applying this bogus test to the present application. For example, under the Examiner's restriction a claim to bicalutamide form II (e.g. claim 1 of group I) is independent and distinct from a claim to a mixture of bicalutamide form II with other bicalutamide forms (e.g. claim 13 in Group II), even though the first claim dominates (overlaps) the second. A reference showing the composition of claim 12

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would also show the crystalline compound of claim 1; hence contradicting the Examiner's rationale. No explanation or analysis is offered by the Examiner to explain such a position.

Finally, because all claims relate to a bicalutamide molecule, the search is not broad or diverse, but rather the same or virtually the same for all claims. The Examiner would have to search for the structure of bicalutamide whether examining group I or group II, etc. Again, because the Examiner is mistaken in believing that a Markush group of divergent compounds is being claimed, the Examiner's assertion of a searching hardship is likewise erroneous.

Having failed to make the proper showing of independent and distinct inventions and having failed to show any extra burden whatsoever in search and examination, the Examiner's restriction requirement and election of species are clearly in error and should be withdrawn. Nonetheless, in order to be fully responsive, applicants provisionally elect, with traverse as noted above, Group I, claims 1-10 and 14-22. While the further required election of species is not understood, for safety sake, applicants elect the species bicalutamide in crystalline form II.

For the reasons set forth above, the Examiner has provided no legally cognizable basis for restricting the present application and all claims should be searched and examined in a single application. Reconsideration and withdrawal of the restriction requirement and election of species are requested.

#### **IDS Previously Filed**

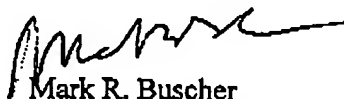
The Office Letter cover sheet indicates this communication is responsive to the application filing on September 12, 2003. But applicants point out that an Information Disclosure Statement (IDS) was filed on January 14, 2004. If the Examiner does not have this

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IDS, he is encouraged to contact applicants' undersigned representative and a copy will be promptly provided along with proof of prior filling.

Should the Examiner have any questions regarding this application, the Examiner is requested to contact applicants' representative, Mark R. Buscher (Reg. No. 35,006) at telephone number 703 753 5256.

Respectfully submitted,



Mark R. Buscher  
Registration No. 35,006

P.O. Box 161  
Catharpin, VA 20143  
703 753 5256